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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/524,228  | 02/09/2005  | Alan John Johnstone  | 205139 (8830-308)   | 1559             |
| 7590<br>Gregory J Lavorgna<br>Drinker Biddle & Reath<br>One Logan Square<br>18th & Cherry Street<br>Philadelphia, PA 19103-7595 |             |                      |                     |                  |
| 06/09/2009  |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| NATNITHITHADHA, NAVIN   |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
| 3735  |             |                      |                     |                  |
| MAIL DATE   |             | DELIVERY MODE        |                     |                  |
| 06/09/2009  |             | PAPER                |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/524,228

**Applicant(s)**

JOHNSTONE, ALAN JOHN

**Examiner**

NAVIN NATNITHADHA

**Art Unit**

3735

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 20 March 2009.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3,5-9 and 11 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 1-3,5-9 and 11 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 09 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☒ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO/SB008)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application  
6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Response to Amendment***

1. According to the Amendment, filed 20 March 2009, the status of the claims is as follows:

Claim 2 is as originally filed;

Claims 1, 3, 5-9, and 11 are previously presented; and

Claims 4, 10, and 12-23 are cancelled.

### ***Response to Arguments***

2. Applicant's arguments, see Remarks, pp. 5-7, filed 20 March 2009, with respect to the rejection of claims 1-3, 5-9, and 11 under 35 U.S.C. 102(b) as being anticipated by Khuri et al, U.S. Patent No. 6,567,679 B1 ("Khuri"), have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-3, 5-9, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear as to whether a device or a person performs the process limitation "determining the presence or severity of ischemia in the tissue".

It is not clear as to whether a device or a person performs the process limitation "directly measuring intracompartemental pH in the tissue".

It is not clear as to whether a device or a person performs the process limitation "using the intracompartmental pH measurement to diagnose the pathological condition."

It is not clear how "determining the presence or severity of ischemia in the tissue" can be performed "by inserting a pH sensor into the tissue". This does not seem to be possible. Further explanation or amendment is required.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 1-3, 5-9, and 11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-3, 5-9, and 11 are rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter because these are method or process claims that neither transforms underlying subject matter, such as a particular article or materials, to a different state or thing, nor tied to another statutory class, such as a particular machine or apparatus. *See In re Bilski*, 545 F.3d 943, 88 USPQ2d 1385 (Fed. Cir. 2008); *Diamond v. Diehr*, 450 U.S. 175, 184 (1981) (quoting *Benson*, 409 U.S. at 70); *Parker v.*

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*Flook*, 437 U.S. 584, 588 n.9 (1978) (citing *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876)). See also *In re Comiskey*, 499 F.3d 1365, 1376 (Fed. Cir. 2007) (request for rehearing *en banc* pending).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-3, 5-9, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiddian-Greene et al, U.S. Patent No. 6,238,339 B1 ("Fiddian-Greene"), in view of Sacristan et al, U.S. Patent No. 5,158,083 A ("Sacristan").

Claims 1-3, 5-9, and 11: Fiddian-Greene teaches the following:

a method of diagnosing a pathological condition of a patient's body tissue (see Abstract), the method comprising:

determining the presence or severity of ischemia in the tissue by inserting a pH sensor 42 into the tissue, e.g. an "internal organ" (see col. 5, ll. 49-57, and col. 18, ll. 2-65),

indirectly measuring intracompartmental pH in the tissue (see col. 18, ll. 2-65),  
and

using the intracompartmental pH measurement to diagnose the pathological condition (see col. 18, ll. 2-65);

wherein the pH sensor 42 consists of a single probe 40 mounted on a catheter 22 (see fig. 2).

Fiddian-Greene does not teach "directly measuring intracompartmental pH in the tissue". However, Sacristan teaches a pH sensor 14 consisting of a single probe 10 mounted on a catheter (see figs. 1 and 2, and col. 5, l. 65, to col. 6, l. 4), wherein the pH sensor 14 directly measures intracompartmental pH in a tissue using an electrode (see col. 3, ll. 35-57). Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Fiddian-Greene's probe 40 with Sacristan's probe 10 in order to reliably measure pH values accurately for the purpose of diagnosing intestinal ischemia. In addition, the combination would offer predictable results in the measurement of pH values, which both teachings attempt to measure.

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The other patents cited in the PTO-892 teach subject matter related to the Applicant's claims. The Examiner suggests reviewing these patents before responding to the present Office Action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Navin Natnithithadha/  
Patent Examiner, Art Unit 3735  
06/06/2009